AMERICAN® REGENT

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IMPORTANT DRUG SAFETY INFORMATION

READ PRIOR TO USE OF THIS PRODUCT

April 16, 2013

Re: Potential for crystallization of Sodium Phosphates Injection, USP
3 mM/mL Phosphorus; 4 mEq/mL Sodium

5 mL Single Dose Vials, NDC # 0517-3405-25
15 mL Single Dose Vials, NDC # 0517-3415-25
50 mL Single Dose Vials, NDC # 0517-3450-25

Dear Healthcare Professional:

Luitpold Pharmaceuticals, Inc. would like to inform you about the potential for crystallization of Sodium Phosphates Injection, USP, Single Dose Vials. All lots of Sodium Phosphates Injection, USP, Single Dose Vials manufactured by Luitpold Pharmaceuticals, Inc. (distributed by American Regent, Inc.) in commercial distribution contain a saturated solution of sodium phosphates which are subject to crystallization when stored at temperatures below the labeled storage conditions: "*Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).*"

If crystallization occurs when stored below labeled storage conditions, potential adverse events after intravenous administration of crystals may include damage to blood vessels in the lung, localized swelling, and granuloma formation.

TO PREVENT THIS POSSIBILITY PLEASE STORE THIS PRODUCT AS DIRECTED AND AVOID FREEZING OR EXPOSURE TO COLD TEMPERATURES.

As a precautionary measure, a filter must be used for withdrawal and administration of all lots of this product.

The following procedure must be used for preparation and administration of **ALL** lots of Sodium Phosphates Injection, USP, distributed by American Regent, Inc.

1. Perform a visual inspection on the vial prior to withdrawal of the contents.
   DO NOT USE IF CRYSTALS/PARTICLES ARE PRESENT. DISCARD THE VIAL.
   USE A NEW VIAL.
2. Use a 5 micron filter needle to withdraw the required calculated volume of Sodium Phosphates Injection, USP.
3. Remove the filter needle and attach a standard needle to the syringe before adding to a larger volume of intravenous (IV) fluid and prior to patient administration.
   NOTE: Sodium Phosphates Injection, USP is to be administered intravenously only after further dilution in a larger volume of IV fluid.
4. Visually inspect the final IV admixture solution.
   DO NOT USE IF CRYSTALS/PARTICLES ARE VISIBLE. DISCARD THE IV ADMIXTURE SOLUTION. USE A NEW VIAL AND REPEAT STEPS 1-3.
5. Use a 0.22 micron in-line filter when administering the final IV admixture to patients.
6. For lipid containing admixtures, the use of a 1.2 micron in-line filter is recommended.

If crystals/particles are observed or if you require additional information, please contact American Regent Professional Services Department at 1-877-788-3232 (Monday-Friday: 9:00am-5:00pm ET) or e-mail at: inquiry@americanregent.com.

Adverse events or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Reporting program online, by regular mail, or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form
- Fax: 1-800-FDA-0178

We apologize for any inconvenience that you may experience and appreciate your cooperation in this matter.

Sincerely yours,

Walter A. Tozzi, R.Ph., MS, MBA
Vice President of Marketing & Professional Services

DISP APR 2013